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Continuation sheets of this form	0
Description	9
Claim(s)	8
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Priority documents	–
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Statement of inventorship and right to grant of a patent (Patents Form 7/77)	2 PAGES ✓
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12. Name, daytime telephone number and e-mail address, if any, of person to contact in the United Kingdom DR. RICHARD SKIPPER (01962) 712143
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Moulding Process

Field of the invention

The present invention relates to a method and apparatus for producing polymer products such as a plurality of ophthalmic lenses and to products and ophthalmic lenses thus produced.

Background art

The conventional method of producing ophthalmic lenses is to form a lens blank by polymerisation of liquid monomers in a mould and to subsequently mechanically lathe the lens blank into a finished lens and to polish the lens to remove imperfections. This method is labour-intensive and expensive.

In recent times, double-sided cast moulding (DSCM) processes have been developed. These processes generally involve the initial production (by moulding) of single-use male and female moulds. Liquid monomers are then deposited into the female mould and the male and female moulds are mated together. The monomers are then cured by heating to form the desired polymer lens (the term 'cured' means that the material being cured is rendered insoluble in a solvent in which it was previously soluble and the term is thus a generic term covering more specific terms such as polymerisation, crosslinking, vulcanisation etc.). The lens is removed from the mould and is washed to extract unreacted monomers and/or solvents. The moulds are then discarded and the lenses are packed in final packs.

It is to be noted that the controllable moulding process in such a DSCM process is the moulding of the single-use moulds rather than that of the lenses themselves. The most common way of producing the single-use moulds is to produce them between two platens with removably mounted, precisely machined inserts

mounted on the platens. A change of mould shape (in order to produce a lens with different optical qualities) is achieved through a change of inserts in the moulding platen. The inserts are generally created on a precision lathe and are polished to remove surface imperfections. Some particular lens optical qualities are created by controlling the orientation of the male to the female mould.

Thus in a DSCM process, it is the shapes of the disposable moulds which determine the shape and power of the final lens.

US 5,508,317 discloses an improvement to standard DSCM in which an aqueous solution of prepolymer is introduced into the mould and curing is effected by photo-crosslinking. It is claimed that this gives the advantage of allowing the washing/extraction step of standard DSCM to be dispensed with.

Other improvements which have been proposed to DSCM include making one of the moulds reusable and making at least one of the moulds UV-transparent to allow UV curing.

WO 98/42497 discloses the curing of lenses produced using a DSCM process by the use of UV alone.

US 4,673,539 and US 4,786,446 disclose a different production process approach involving creating a shaped thermoplastic hydrogel precursor by the thermoforming of a particular form of uncrosslinked polymer (one containing the product of an ethylenically-unsaturated monomer bearing at least one trihaloacetoxy-substitute group), subsequently solvolyzing the precursor in the presence of a diluent in order to form a polymeric shaped article and finally hydrating the shaped article to provide an ophthalmic lens. This process is claimed to produce lenses with high and controllable water sorbency characteristics.

DSCM processes suffer from problems with quality variation in production caused both by control of mould quality in the two-

step casting procedure and by variability in the curing process. In the practical environment of a commercial production process, the curing process is always subject to variations in monomer mixtures and variations in monomer mixture components. A practical curing process is also subject to changes in cure rates due to fluctuations in energy of the (normally thermal) curing source.

All prior art processes suffer from problems of manufacturing efficiency – being, at best, batch processes requiring significant human involvement and, at worst, effectively custom-manufacturing processes requiring skilled operators for each and every process step. Due to this, the cost of production of ophthalmic lenses is relatively high.

It is an object of this invention to provide a method for producing ophthalmic lenses with improved manufacturing efficiency compared to prior art methods. In particular, the method of the current invention provides increased consistency and quality of production as well as a reduction in the quantity of process steps required when compared with prior art methods.

It is a further object of this invention to reduce the quantity of material consumed by the moulding and curing process for an ophthalmic lens and thus, in this way, to reduce the environmental impact of the moulding and curing process.

It is a further object of this invention to also reduce the environmental impact of the moulding and curing process by reducing the amount of wet-chemistry and associated chemical waste products when compared with prior art processes.

Summary of the Invention

The present invention overcomes the problems mentioned above through provision of a method of producing a plurality of ophthalmic lenses according to claim 1.

Further desirable features and desirable embodiments as well as an apparatus for executing the method of the invention, ophthalmic lenses produced using the method and/or apparatus and a method of producing at least one substantially sterile polymer product are detailed in claims 2 to 46.

The current invention has many advantages over prior art production methods for ophthalmic lenses:

When using the current invention, there is no loss of precision in lens shape due to allowances that must be made in prior art methods both for shrinkage in the moulds as they cool and for shrinkage in initial monomer volume due to polymerisation (typically a shrinkage of roughly 16% which is very difficult to control accurately).

When using the current invention, there is no need to store and maintain an inventory of single-use moulds, which are not currently in use.

Since there is no need for producing disposable moulds, which are not part of the final product, the current invention produces a dramatic reduction in waste material.

Due to using more easily-controllable process steps, lenses produced using the current invention have an improved accuracy of lens power, improved surface quality and improved power consistency vis-à-vis those produced using prior art methods.

Some particular embodiments of the current invention provide improved sterilisation, packaging and in-line inspection steps

over prior art methods of production. These improvements can also lead to a reduced manufacturing area requirement.

Compared to known methods of using reusable glass moulds, the current invention has the advantage that mould washing and inspections for mould cleanliness is not required as frequently.

In the known methods which use curing by UV alone, UV-absorbing agents cannot be incorporated into lenses, since these then inhibit the polymerisation process. In the current invention, non-UV forms of irradiation may be employed when it is desired to create lenses containing such UV-absorbing agents.

Other aspects and advantages of the invention will be clear from a study of the following detailed description and drawings in which a particular embodiment of the invention is described consisting of a manufacturing process for contact lenses, wherein a contact lens is used as a particular example of an ophthalmic lens and e-beam irradiation is used as a particular example of a means of application of high energy.

Brief Description of Drawings

Figure 1: A schematic diagram of a contact lens manufacturing apparatus according to an embodiment of the invention

Detailed description

Figure 1 shows a schematic representation of an embodiment of the invention. A roll of uncrosslinked polymer in the form of sheet, 1, is provided and is transported to a thermoforming area, 14. Prior to entering the thermoforming area the polymer

sheet is inspected by means of an automatic vision system, 2, for significant defects, such as tears, that would result in an unsatisfactory final product.

The polymer sheet is heated to a temperature where it is easy to shape the polymer into the desired shape as defined by inserts on the moulding platens, 3 and 9, in the thermoforming process and yet the polymer sheet still retains sufficient strength for it to be manipulated through the process.

The polymer sheet is then passed through the thermoforming area where platens, 3 and 9, containing the optical quality inserts, shape the polymer sheet into the desired form. Depending on the properties of the polymer sheet the inserts and the platens may be cooled or heated as required to obtain the required flow and optical clarity in the shaped part. The use of pressure or vacuum through the platens or inserts may also be used to achieve the desired shape. The optical inserts and their bodies, which fit into the platen, are so designed that the formed parts are not fully detached from the original polymer sheet and that after the forming process has been completed the formed parts are moved forward with the polymer sheet, 12.

The formed parts are then inspected by means of an automated vision system, 4, for defects. The polymer sheet with formed parts may then be stored for use in the future or processed immediately as a continuous or semi-continuous process by passing it through an electron beam at station 5. The exposure of the polymer sheet and the formed parts to the electron beam is so controlled that the polymer becomes as crosslinked as is required and if necessary also as sterile as is required. The formed parts are separated from the polymer sheet and deposited into final packages within a sterile environment — schematically shown as occurring at station 5 in figure 1, although it is to be noted that packaging may occur at a separate station from electron beam irradiation (not shown).

The final packages are manufactured and/or treated at station 6 so that they are effectively sterile and are maintained within an environment that keeps them, and the formed parts, sterile. The final packages are transported, 13, to a position to allow transfer of the formed parts into the final packages. The final packages holding the formed parts are transported within the sterile environment to a dosing station, 7, where aseptic or sterile packaging/hydration solution is added. The final packages, solution and formed parts are then sealed at station, 8, also within the sterile area, with a sterile foil before leaving the process area for final labelling.

"Ophthalmic lenses", as used herein, refers to any medical or vision correction devices that are used in the ocular environment, including contact lenses, intraocular lenses, corneal onlays and inlays, ocular drug delivery devices, ocular wound healing devices and the like.

The crosslinking portion of the lens production process involves the exposure of a dry lens shape made from the polymer to a high energy source. "High energy", as used herein, refers to many different forms and includes sources that generate, but is not limited to, thermal, I.R., U.V., microwave, gamma, ultrasonic and electron beam radiation.

"Crosslinking", as used herein, is used to describe the process in which a soluble polymer is converted into an insoluble form through the formation of bonds, i.e. crosslinks, between the polymer chains. It will be obvious to those skilled in the art that the insoluble form may, in addition to crosslinked structures, contain structures known as grafted polymers or entangled polymers.

One purpose of crosslinking, as used herein, is to permit the crosslinked dry lens to form a stable wet lens, as required by the design, and in doing so provide power correction to a wearer.

For polymers that are water-soluble the crosslinked polymer is known as a hydrogel.

"Polymer", as used herein, refers to the material from which the initial lens shape is produced and includes copolymers, mixtures of polymers, interpenetrating network systems, polymer systems that are already partially crosslinked, polymer to which additives have been added to assist in the crosslinking reaction, to reduce UV transmission, for therapeutic purposes, to add colour for cosmetic reasons and the like.

The energy source and radiation used for crosslinking may vary, together with time of exposure, depending on the polymer composition and the properties required. In one preferred example of an ophthalmic lens, that of a hydrated contact lens, the final lens may comprise water content from 20 to 75%, by weight. It can be generally assumed that for a given polymer the crosslink density of the lens will control the water content of the lens, i.e. the greater the crosslink density the lower the water content.

In another example it is possible that the required levels of both crosslink density and sterility can be achieved simultaneously through exposure to radiation.

It is generally desirable that the crosslinking process is achieved as quickly as possible, preferably in less than 10 minutes, more preferably in less than 4 minutes, and even more preferably in less than one minute. In some polymer formulations it may be necessary for there to be more than one cycle to meet quality and performance requirements. At the same time it is also necessary to ensure the safety of the personnel operating the process and of the general environment. For these reasons the level of energy used for the crosslinking process may be lower than that practically

required for the necessary level of crosslinking in one pass; this is compensated for by multiple passes.

Where the radiation crosslinking is effected by exposure to an electron beam or to gamma rays, additives, known as prorads, may be incorporated into the polymer at a level of 0.2 to 5% by weight for the purpose of promoting crosslinking. These compounds may be poly-functional vinyl or allyl compounds such as triallyl cyanurate, triallyl isocyanurate or pentaerithritol tetramethacrylate.

Radiation dosages will depend on the response of the polymer being irradiated and on the level, if any, of prorad. Typical dosages will be in the range 20 to 800 kGy, preferably 20 to 500 kGy, e.g. 20 to 200 kGy and particularly 40 to 120 kGy.

The inventive concept of the present invention may also be applied to products other than ophthalmic lenses, for example polymer products that may be thermoformed and require to be packed in sterile conditions. Such application examples include artificial limbs, joints and other prostheses. Other applications include polymer containers for foods, especially those that are dehydrated, e.g. dried milk and re-hydration materials, where purity and long life stability are requirements.

CLAIMS

1. A method of producing a plurality of ophthalmic lenses, which comprises the following process steps:
   - A Providing a polymer, said polymer being a polymer that comprises crosslinkable groups, but which is substantially uncrosslinked;
   - B Physically forming said polymer into said plurality of ophthalmic lenses;
   - C Applying high energy to said plurality of ophthalmic lenses whereby said polymer is crosslinked to a predetermined, desired crosslink density.

2. A method of producing a plurality of ophthalmic lenses according to claim 1, in which said polymer is provided in solid phase.

3. A method of producing a plurality of ophthalmic lenses according to claim 2, in which said polymer is provided in the form of a sheet of material.

4. A method of producing a plurality of ophthalmic lenses according to any of claims 1 to 3, in which said polymer is substantially water-soluble and said ophthalmic lenses are soft contact lenses.

5. A method of producing a plurality of ophthalmic lenses according to any of the preceding claims, in which said polymer is chosen from the group consisting of polyvinyl alcohol or a copolymer of polyvinyl alcohol and polyvinyl acetate or polyethylene-maleic-anhydride or polymethyl-hydroxy-propyl-cellulose or copolymers of methyl acrylate or ethyl acrylate with ethylene or their hydroxy derivatives.

6. A method of producing a plurality of ophthalmic lenses according to any of the preceding claims, in which said physical forming step B involves any one of the group of

physical forming processes from the group consisting of thermoforming or vacuum forming or pressing or hot moulding or cold moulding or compression moulding or injection moulding

7. A method of producing a plurality of ophthalmic lenses according to any of claims 1 to 5, in which said physical forming step B comprises the following sub-steps:

B.1 Heating said polymer to a temperature that

a) is near to the softening temperature of the polymer, whereby thermoforming of said polymer is possible, but

b) is below the melting point of said polymer, whereby the physical integrity of said polymer is maintained; and

B.2 Thermoforming said plurality of ophthalmic lenses through application of pressure to said polymer.

8. A method of producing a plurality of ophthalmic lenses according to claim 7, in which said thermoforming sub-step involves compression of the polymer between two forms or platens.

9. A method of producing a plurality of ophthalmic lenses according to any of claims 4 to 8 in dependence upon claim 3, in which subsequent to said physical forming step B, said plurality of ophthalmic lenses remain at least partially attached to said sheet of material.

10. A method of producing a plurality of ophthalmic lenses according to claim 9, in which said sheet of material is used as a transport medium or carrying mechanism for said plurality of ophthalmic lenses through multiple steps of the method of production.

11. A method of producing a plurality of ophthalmic lenses according to any of the preceding claims, in which the physical forming step B involves the use of moulds and

said polymer is placed between said moulds which are pressed together to form said plurality of ophthalmic lenses.

12. A method of producing a plurality of ophthalmic lenses according to claim 11, in which the application of high energy step C occurs while the polymer is in said moulds.

13. A method of producing a plurality of ophthalmic lenses according to claim 11, in which the application of high energy step C occurs after the plurality of ophthalmic lenses have been removed from the moulds.

14. A method of producing a plurality of ophthalmic lenses according to claim 13, in which said plurality of ophthalmic lenses are transported from the moulds to the high energy application area without further human contact or handling.

15. A method of producing a plurality of ophthalmic lenses according to any of the preceding claims, in which the application of high energy step C is arranged to also sterilise said plurality of ophthalmic lenses.

16. A method of producing a plurality of ophthalmic lenses according to any of the preceding claims, in which the application of high energy step C involves irradiation of the plurality of ophthalmic lenses by a form of high energy chosen from the group consisting of electron beam irradiation or gamma irradiation or microwave irradiation or ultraviolet irradiation or infrared irradiation or thermal irradiation or ultrasound irradiation.

17. A method of producing a plurality of ophthalmic lenses according to any of the preceding claims, which comprises the further step of:

D. transferring the plurality of ophthalmic lenses to a plurality of final packs.

18. A method of producing a plurality of ophthalmic lenses according to claim 17, in which, before the transferring step D, the final packs are sterilised.

19. A method of producing a plurality of ophthalmic lenses according to claim 17 or 18, in which, either before or after the transferring step D, aseptic or sterile solution is added to the sterile final packs, which solution acts to hydrate the lenses.

20. A method of producing a plurality of ophthalmic lenses according to any of claims 17 to 19, in which the polymer undergoes a chemical reaction, such as hydrolysis, in the final pack in order to form the final material.

21. A method of producing a plurality of ophthalmic lenses according to any of claims 17 to 20, in which, either before or after the transferring step D, the ophthalmic lenses are washed to remove soluble material.

22. A method of producing a plurality of ophthalmic lenses according to any of claims 17 to 19, in which the ophthalmic lenses are not washed to remove soluble material.

23. A method of producing a plurality of ophthalmic lenses according to any of preceding claims 17 to 22, in which all process steps subsequent to the application of high energy step C are carried out in a suitable environment to ensure the sterility of the final product and the final packs are sealed prior to leaving said suitable environment.

24. A method of producing a plurality of ophthalmic lenses according to claim 23, in which all process steps subsequent to the application of high energy step C are carried out without further human contact or handling.

25. A method of producing a plurality of ophthalmic lenses according to claim 3, or to any of claims 4 to 24 in dependence on claim 3, which method is automated or semi-automated to run in a continuous or semi-continuous manner.

26. A method of producing a plurality of ophthalmic lenses according to any of the preceding claims, which further involves quality control inspections on the dry ophthalmic lenses only.

27. A method of producing a plurality of ophthalmic lenses according to any of the preceding claims, which involves either visual quality control inspections or quality control inspections using an optical system.

28. A method of producing a plurality of ophthalmic lenses according to any of the preceding claims in which the polymer contains additives that react to the application of high energy to improve crosslinking efficiency.

29. An ophthalmic lens produced according to a method of producing a plurality of ophthalmic lenses according to any of the preceding claims.

30. A soft contact lens produced according to a method of producing a plurality of ophthalmic lenses according to any of the preceding claims.

31. An apparatus for carrying out a method of producing a plurality of ophthalmic lenses according to any of claims 1 to 28 comprising:

- first transporting means for transporting said polymer to
- physical forming means for physically forming said polymer into said plurality of ophthalmic lenses;

- high energy application means for applying high energy to said ophthalmic lenses.

32. An apparatus according to claim 31 which further comprises:
- second transporting means for transporting said plurality of ophthalmic lenses from said physical forming means to said high energy application means.

33. An apparatus according to either of claims 31 or 32 in which said transporting means comprises driven and/or undriven roller means for transporting said polymer provided in the form of a sheet of material according to claim 3.

34. An apparatus according to any of claims 31 to 33 in which said physical forming means comprises a plurality of forms or platens arranged so as to press together to form the polymer into the ophthalmic lenses.

35. An apparatus according to claim 34 in which at least one of said plurality of forms or platens is provided with heating means whereby said polymer may be heated in order to facilitate physical forming of the polymer into the ophthalmic lenses.

36. An apparatus according to either of claims 34 or 35 in which said physical forming means consists of a plurality of platens which are removably connectable with a plurality of male and female inserts, which inserts are formed to appropriate shapes to form the ophthalmic lenses to desired optical specifications.

37. An apparatus according to claim 36 in which the inserts are arranged such that pressure (either positive or negative) may be applied through them.

38. An apparatus according to any of claims 31 to 37 which further comprises packaging means for transferring said ophthalmic lenses from said high energy application means into final packs.

39. An apparatus according to claim 38 in which said packaging means is arranged to carry out packaging in an substantially sterile environment.

40. An apparatus according to either of claims 38 or 39 in which said packaging means comprises means for removing said ophthalmic lenses from a sheet of material, when said polymer is provided in the form of a sheet of material according to claim 3 and said sheet of material is used as a transport medium or carrying mechanism according to claim 10.

41. An apparatus for carrying out a method of producing a plurality of ophthalmic lenses according to any of claims 1 to 28 comprising:

- first transporting means for transporting said polymer to
- physical forming means for physically forming said polymer into said plurality of ophthalmic lenses;
- an electron beam irradiation means for irradiating the plurality of ophthalmic lenses.

42. An ophthalmic lens produced by an apparatus according to any of claims 31 to 41.

43. A soft contact lens produced by an apparatus according to any of claims 31 to 41.

44. A method of producing at least one substantially sterile polymer product, which comprises the following process steps:

A Providing a polymer, said polymer being a polymer that comprises crosslinkable groups, but which is substantially uncrosslinked;

B Physically forming said polymer into said at least one substantially sterile polymer product;

C Applying high energy to said at least one substantially sterile polymer product whereby said polymer is simultaneously crosslinked to a predetermined, desired crosslink density and sterilised to a predetermined, desired level of sterility.

45. A medical device produced according to the method of claim 44.

46. A food packaging product produced according to the method of claim 44.

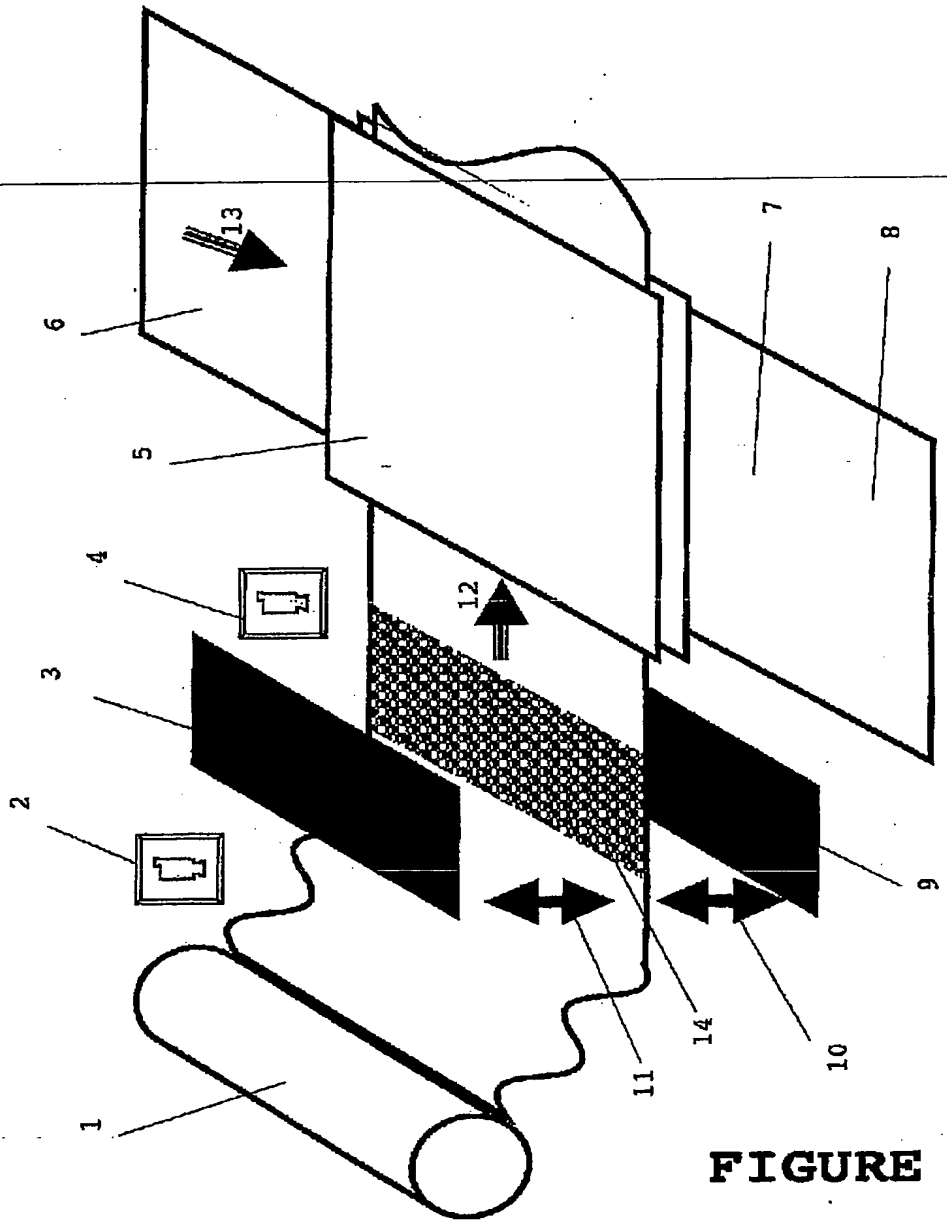

FIGURE 1